

Message Text

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ORIGIN HEW-06

INFO OCT-01 ARA-10 EA-09 ISO-00 OES-05 EB-07 COME-00 /038 R

DRAFTED BY DHEW/FDA:JRWEINROTH, M.D.:AMS

APPROVED BY OES/APT/BMP:MBEAUBIEN

DHEW/OIH:MACODDING

EA/PRCM:OVARMSTRONG (INFO)

ARA/CAR:DASTRASSER (INFO)

----- 023029

R 142250Z NOV 75

FM SECSTATE WASHDC

TO AMEMBASSY SANTO DOMINGO

AMCONSUL HONG KONG

UNCLAS STATE 270734

E.O. 11652: NA

TAGS: OGEN ETRD TBIO DR HK

SUBJ: FDA ADVISORY - VOLUNTARY RECALL, LARGE VOLUME PARENTERAL
SOLUTION (PH OF PRODUCT DOES NOT MEET U.S.P. REQUIRE-
MENTS, PARTICULATE MATTER PRESENT IN BOTTLES).

1. FDA ADVISES THAT THE FOLLOWING IS BEING RECALLED BY
MANUFACTURER:

PRODUCT: NORMAL SALINE INJECTION, U.S.P. 1000 ML., CLEAR GLASS
LVP BOTTLE LABELED IN PART: "MCGAW NORMAL SALINE, MCGAW LABORA-
TORIES, DIVISION OF AMERICAN HOSPITAL SUPPLY CORPORATION,
GLENDALE, CALIFORNIA 91201 X MILLEDGEVILLE, GEORGIA 31061 -
STERILE, NON-PYROGENIC SODIUM CHLORIDE INJECTION U.S.P. XXX".

LOT NUMBERS: A5E361, A5E362, A5E363, A5E364, A5E392

EXPIRATION DATE: JUNE 1979

PRODUCT ID NO.: 5-4000

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MANUFACTURER/REVALLING FIRM: MCGAW LABORATORIES, 2525 MCGAW

AVENUE, IRVINE, CALIFORNIA 92711.

REASON FOR ADVISORY/RECALL: A YELLOW PRECIPITATE HAD BEEN FOUND IN SOME BOTTLES ALONG WITH A YELLOW DISCOLORATION OF THE AIR TUBE. THE BOTTLES TESTED AFTER THE PROBLEM WAS NOTED, FAILED THE TEST FOR U.S.P. TYPE II GLASS. THE PH WAS ALSO OUT OF LIMITS AND ABOVE 8.2. TESTING BY THE FIRM FOUND THAT THE PRECIPITATE APPEARED TO BE BUTYLATED HYDROXYTOLUENE (BHT). BIOLOGICAL TESTS FOUND THAT THE PRECIPITATE WAS NON-TOXIC, NON-HEMOLYTIC, AND DOES NOT CAUSE AGGREGATION OF ERYTHROCYTES.

2. POSTS ARE REQUESTED TO CONTACT FOREIGN CONSIGNEES TO DETERMINE IF THEY HAVE RECEIVED RECALL LETTER FIRM ISSUED ON OCTOBER 31, 1975 REGARDING THIS PROBLEM. ANY QUESTIONS CONSIGNEES MAY HAVE REGARDING THIS ADVISORY SHOULD BE DIRECTED TO THE FIRM.

3. FOREIGN CONSIGNEES AS FOLLOWS:

J. GASSO GASSO C. POR A
DOMINICAN REPUBLIC

Y.C. WOO AND CO.
HONG KONG. KISSINGER

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NNN

Message Attributes

Automatic Decaptioning: X
Capture Date: 01 JAN 1994
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: DRUGS, RECALLS
Control Number: n/a
Copy: SINGLE
Draft Date: 14 NOV 1975
Decaption Date: 01 JAN 1960
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Authority: n/a
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 JAN 1960
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1975STATE270734
Document Source: CORE
Document Unique ID: 00
Drafter: JRWEINROTH, M.D.:AMS
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Film Number: D750398-0691
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1975/newtext/t19751144/aaaabnpr.tel
Line Count: 85
Locator: TEXT ON-LINE, ON MICROFILM
Office: ORIGIN HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 2
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Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: n/a
Review Action: RELEASED, APPROVED
Review Authority: GolinoFR
Review Comment: n/a
Review Content Flags:
Review Date: 04 AUG 2003
Review Event:
Review Exemptions: n/a
Review History: RELEASED <04 AUG 2003 by ReddocGW>; APPROVED <04 MAR 2004 by GolinoFR>
Review Markings:

Margaret P. Grafeld
Declassified/Released
US Department of State
EO Systematic Review
06 JUL 2006

Review Media Identifier:
Review Referrals: n/a
Review Release Date: n/a
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
Secure: OPEN
Status: NATIVE
Subject: FDA ADVISORY - VOLUNTARY RECALL, LARGE VOLUME PARENTERAL SOLUTION (PH OF PRODUCT DOES NOT MEET U.S.P. REQUIRE-
TAGS: OGEN, ETRD, TBIO, DR, HK
To: SANTO DOMINGO HONG KONG
Type: TE
Markings: Margaret P. Grafeld Declassified/Released US Department of State EO Systematic Review 06 JUL 2006